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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,463	04/12/2004	Dale B. Schenk	15270J-004754US	4597

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
WANG, CHANG YU	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 09/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/823,463	SCHENK, DALE B.	
	Examiner	Art Unit	
	Chang-Yu Wang	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *69-110* is/are pending in the application.

4a) Of the above claim(s) *106-110* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *69-105* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *April 12, 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Status of Application

1. Claims 69-110 are pending. Claims 106-110 are withdrawn from consideration as being drawn to non-elected inventions. Claims 69-105 are under examination in this office action.

Election/Restrictions

2. Applicant's election without traverse of Group I in the reply filed on May 3, 2005 is acknowledged.

3. Claims106-110 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Groups II and III, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 3, 2005.

Priority

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows:

5. This application repeats a substantial portion of prior Application No. 09/580,015, filed May 26, 2000, and adds and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

6. The instant application claims the compositions comprising antibodies against soluble aggregated amyloid-β protein, soluble non-fibrillar aggregated amyloid β-protein, soluble aggregated amyloid β1-42 and ADDLs, as well as the assemblies, ADDLs, for aggregated amyloid β1-42, which are not presented in the application No. 09/580,015, filed May 26, 2000, and thus considered as new matters. The specification only discloses the antibodies against aggregated amyloid β protein 1-42, AN1792, and defines the aggregated amyloid β protein 1-42, AN1792, as "Disaggregated or monomeric Aβ means soluble, monomeric peptide units of Aβ. One method to prepare monomeric Aβ is to dissolve lyophilized peptide in neat DMSO with sonication. The resulting solution is centrifuged to remove any insoluble particulates. Aggregated Aβ is a mixture of oligomers in which the monomeric units are held together by noncovalent bonds." (see p.12 in the specification.).

7. Therefore, the priority for the above claimed subject matter is April 12, 2004.

Oath/Declaration

8. "A continuation or divisional application filed under 37 CFR 1.53(b) (other than a continuation-in-part (CIP)) may be filed with a copy of the oath or declaration from the prior nonprovisional application. See 37 CFR 1.63(d)(1)(iv)." "If the examiner determines that the continuation or divisional application contains new matter relative to the prior application, the examiner should so notify the applicant in the next Office action. The examiner should also (1) require a new oath or declaration along with the surcharge set forth in 37 CFR 1.16(e); and (2) indicate that the application should be redesignated as a continuation-in-part." See MPEP§ 602.05.

9. This application presents a claim for subject matter not originally claimed or embraced in the statement of the invention. The specification only discloses the antibodies against aggregated AN1792, and does not disclose any knowledge of antibodies recognizing any soluble forms of aggregated Aβ1-42 or ADDLs. A supplemental oath or declaration is required under 37 CFR 1.67. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

10. Therefore, a new oath or declaration is required.

Specification

11. The specification is objected to because it does not describe the claimed subject matter. "In establishing a disclosure, applicant may rely not only on the description and drawing as filed but also on the original claims if their content justifies it. Where subject matter not shown in the drawing or described in the description is claimed in the application as filed, and such original claim itself constitutes a clear disclosure of this subject matter, then the claim should be treated on its merits, and requirement made to amend the drawing and description to show this subject matter. The claim should not be attacked either by objection or rejection because this subject matter is lacking in the drawing and description. It is the drawing and description that are defective, not the claim. It is, of course, to be understood that this disclosure in the claim must be sufficiently specific and detailed to support the necessary amendment of the drawing and description." See MPEP § 608.01 (l).

12. In addition, an appropriate statement is required in the section of the cross-references to related applications in the Specification.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 69-105 are rejected under 35 U.S.C. 102 (b) as being anticipated by Kuo et al. (J. Biol. Chem. 1996. 271:4077-4081) and Klein et al. (U. S. patent application No. 10/166, 856, effective filling date June 11, 2002, published on April 10. 2003).

Kuo et al. teach using a mouse monoclonal antibody 266 to characterize the soluble form of Aβ (N-40, N-42) oligomers in the brain. The antibody used in their ELISA system for detecting Aβ peptides meeting the limitation of the above claims. See P.4078, in the section of ELISA in Experimental procedures.

Klein et al. teach anti-ADDL antibodies generated from soluble non-fibrillar oligomeric assembles of amyloid β protein meeting the limitations of the above claims. See claims 1,2, 4-5,7, 9, 10, 11 and the specification, p. 7, lines 2-4.

The antibodies against to AN1792 and disclosed in the instant specification recognize fibrillar aggregated Aβ1-42. The specification in this instant application has not provided further definition for soluble aggregated amyloid β protein, nevertheless, the reference fairly anticipates because the mouse monoclonal antibody 266 disclosed by Kuo et al is able to detect the soluble form of Aβ. In addition, the anti-ADDLs antibody recognizes the soluble aggregated amyloid β protein, soluble non-fibrillar aggregated amyloid β protein, soluble non-fibrillar oligomeric assembles of amyloid β protein wherein the assembles are ADDLs, and soluble aggregated amyloid β1-42 including AN1792, which also meets the limitation of the claims in this instant application.

Therefore, Claims 69-105 are anticipated by Kuo et al. and Klein et al..

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. Claims 69-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert et al. (Proc. Natl. Acad. Sci. USA. 1998. 95: 6448-6453) in view of Kuo et al. (J.Biol. Chem. 1996. 271: 4077-4081).

Lambert et al. teach soluble and diffusible nonfibrillar ligands derived from Aβ1-42, ADDLs, are more neurotoxic than the fibrillar Aβ. See the abstract. Lambert et al. further suggest that the cell surface protein and signal transduction molecules that mediated ADDLs toxicity

would be important for therapeutical approaches for Alzheimer's disease (see P. 6452, the last paragraph), which includes an antibody against ADDLs to neutralize the ADDLs toxicity.

Lambert et al. do not teach to generate an antibody against ADDLs.

Kuo et al. teach that there are more soluble of Aβ1-42 in the (AD) brain when compared to a normal brain. Kuo et al. further teach that using an antibody to characterize this soluble form of Ab1-42 in the AD brain.

Kuo et al. do not teach the soluble form of Aβ1-42 is related to the more neurotoxic form of ADDLs.

Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to generate an antibody to recognize a more toxic form of Aβ and use it as a therapeutical agent to target the ADDLs, which were suggested by Lambert et al.. The person of ordinary skill in the art would have been motivated to make those modifications because the soluble form of Aβ1-42 including ADDLs is more abundant in the AD brain and ADDLs more neurotoxin and could be a contributory factor for the pathogenesis of AD, and would have expected success in generating an antibody against more neurotoxic and soluble non-fibrillar form of Aβ, which includes ADDLs.

NO CLAIM IS ALLOWED

18. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

19. Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang, Ph.D. whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CYW
September 16, 2005

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER